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REMARKS

Claims 75-134 are pending in the application. Claims 76-81 and 84-96 are allowed. Claims 75, 82, and 83 are rejected by the Examiner. Claims 97-134 are added.

With this amendment, claim 75 is amended. The amendments to the claims are supported throughout the specification including at page 9, lines 19-24 and page 10, lines 2-3. Claims 89, 93 and 94 are amended for proper dependency, without changing the scope of the claimed subject matter. Claim 91 is amended to include accidentally omitted text, without changing the scope of the claim. Claims 97 and 98 are added to further define compositions supported, throughout the specification, including for example on page 40 and 89. The subject matter of claims 53, 54 and 55, and claims 59 and 61, are re-presented herein as new claims 99 -134. The new claims are supported throughout the specification, including the original claims as filed.

Under current restriction practice, once a product claim is found allowable, the claims directed to the process of using that product and the process of making that product (which contain all of the limitations or are dependent from the allowable product claim) will be rejoined. The claims directed to the process of using and making that product must then be fully examined for patentability. MPEP § 821.04.

Claims 75-96 correspond to previously presented claims 1, 5, 6-10, 14, 15, 17, 18, and 40-52. Applicant respectfully asserts that claims 118-130, are directed to a process of using the products of the indicated claims. Claims 97- 117 are directed to a process of making the products of the indicated claims; and therefore should be rejoined now that the subject matter of those claims has been found allowable.

35 U.S.C. § 112

Claim 75 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. This rejection is obviated by amendment. The amended claim 75 now clearly directs the surfactant comprising a block copolymer to be referring to the non-ionic surfactant.

**35 U.S.C. § 103**

Claims 82 and 83 are rejected as allegedly being obvious over the combination of Nath (I.N. 93772, ABSTRACT ONLY) in view of Fost et al. (U.S. Patent No. 5,215,976). Applicants respectfully traverse.

Claim 82 is directed to a spermicidal composition comprising a gel microemulsion containing an oil and water microemulsion and a polymeric hydrogel, wherein the oil and water microemulsion comprises; a lipid, one or more pharmaceutically acceptable surfactants, one or more pharmaceutically acceptable humectants; water and one or more preservatives selected from the group consisting of sodium benzoate, methyl parabens, propyl parabens, thimerisal, and sorbic acid. Claim 82 is directed to the composition of claim 82, wherein the preservative is sodium benzoate.

In order to establish a prima facie case of obviousness, three basic criteria must be met:

- 1) a suggestion or motivation to modify the references or combine the reference teaching;
- 2) the references, when combined, must teach or suggest all of the claim limitations;
- and
- 3) the references, when combined, must provide a reasonable expectation of success.

Applicants submit all of these requirements have not been met.

The Examiner alleges that Nath discloses a spermicidal composition of an oil and water emulsion wherein the oil and water emulsion comprises a surfactant, alkylphenoxypoly(ethylenoxy) ethanol, stearic acid, glycerol and water. The Examiner further alleges Nath discloses a spermicidal composition in a gel form, which comprises a humectant, a hydro-gel, (sodium carboxymethylated cellulose), alkylphenoxypoly(ethylenoxy) ethanol, and water. The Examiner combines the Nath reference with Fost et al. that allegedly discloses phospholipids for use in spermicidal compositions.

- (1) The Examiner has not established that there is a motivation to combine the abstract of Nath with the teaching of Fost, especially where the art teaches away from the combination.

"Applicants submit that the Examiner has not established a motive to combine these references and has not properly taken into account evidence that the art taught away from the methods as claimed by Applicants. In fact, "[A] rejection cannot be predicated on the mere identification . . . of individual components of the claimed invention. Rather, particular findings must be made as to the reason

the skilled artisan, with no known knowledge of the claimed invention, would have selected these components for combination in the manner claimed." Ecolochem Inc. v. Southern Calif. Edison Co., 227 F3d 1361, 1375 (Fed. Cir. 2000). "Obvious to try" is not the standard. Ecolochem at 1374. Applicants submit that cited references implicitly or explicitly do not provide motivation to combine these references."

No suggestion is presented in either Nath nor Fost that synthetic phospholipid-like compounds such as Fost should or can be combined with Nath's spermicidal composition. The teaching of Nath is limited to the english abstract published in CAPLUS provided by the Examiner. Nath teaches spermicidal compositions useful as topical remedies. The compositions of Nath comprise higher unsaturated fatty acids or anionic surfactants in combination with alkylphenoxypoly (ethylenoxy)ethanol (compound I). All of Nath's compositions contain compound I.

Compound I encompasses a family of detergents including nonoxynol-9 (N-9) (nonylphenoxypoly(ethoxy)ethanol). Detergent type spermicides, such as nonoxynol-9, disrupt cell membranes. The major drawback of using N-9 is the disruption of membranes of the epithelial cells and normal vaginal flora leading to increased risks of vaginal or cervical infection, irritation, or ulceration. An advantage of the spermicidal compositions of the present invention is that they do not include irritating detergents, such as N-9, to achieve spermicidal activity. See the specification at page 2, line 16 through page 3 line 2.

Fost also teaches that known spermicidal compounds are irritating and have limited usefulness in personal care and cosmetic products. (Fost, column 1, line 28-33.) There is no motivation to combine the references where Fost teaches against the inclusion of irritating ingredients in personal care products, while the focus of Nath's compositions are known irritants —i.e. compound I. Additionally, Fost makes no suggestion or teaching to combine the synthetic, lipid-like compound with other spermicidal agents.

(2) Even if Fost and Nath are combined, the gel-microemulsion composition of claims 82 and 83 is not taught. The references when combined, do not teach or suggest all of the claim limitations. Claims 82 and 83 are directed to gel-microemulsions. The gel microemulsions comprise an "oil-in-water microemulsion" and a polymeric hydrogel. "Microemulsion" is defined at page 6, lines 16-18 of the specification:

"Microemulsions" are thermodynamically stable, transparent, dispersions of water and oil, stabilized by an interfacial film of surfactant molecules. Microemulsions are characterized by their submicron particle size of 0.1  $\mu\text{m}$  or below.

The combination of Nath with Fost does not teach or suggest the formation of microemulsions. The microemulsion of amended claim 82 is formed from a lipid and a non-ionic surfactant. Nath teaches neither a lipid or a non-ionic surfactant. Fost does not overcome these deficiencies. Fost does not teach non-ionic surfactants. Fost does not teach use of the described phospholipid-like compound to form emulsions. Therefore, the combination of Fost with Nath does not teach or suggest the substitution of the phospholipid-like compound of Fost into the formulations of Nath to form an emulsion. The combination of Fost with Nath also does not teach or suggest the further blend a polymeric hydrogel to form a tertiary structure of the gel-microemulsion claimed in claims 82 and 83.

Furthermore, neither Nath nor Fost, teach the inclusion of a preservative. Fost teaches away from including a preservative because Fost's synthetic phospholipid-like compounds have inherent anti-bacterial and anti-fungal activity. Consequently, any composition incorporating a synthetic lipid-like compound of Fost, would not be motivated to additionally include a preservative such as sodium benzoate.

(3) The combination of Nath with Fost does not support an expectation that a successful microemulsion could be formed from the synthetic phospholipid-like compounds of Fost in Nath's spermicidal composition. The combination of Nath with Fost does not teach the use of lipids as the "oil component" in an oil-in-water emulsion, as used in the present invention. (See page 9, lines 19-21 of the specification). The compositions of Nath comprise higher unsaturated fatty acids or anionic surfactant in combination with alkylphenoxypoly (ethylenoxy)ethanol (compound I), a detergent. Neither Nath nor Fost teach or suggest non-ionic surfactants or other components suitable for forming emulsions with lipids. The synthetic, tertiary amine substituted, lipid-like compositions of Fost are atypical phospholipids. That a successful emulsion could be formed between the Fost compounds and Nath formulation is unclear.

The combination of Fost with Nath fails to teach the claimed gel-microemulsion. The teachings of the references are incompatible, and do not teach all the elements of the claims. The claimed gel-microemulsion of claims 82 and 83 is not rendered obvious by the combination of Fost with Nath.

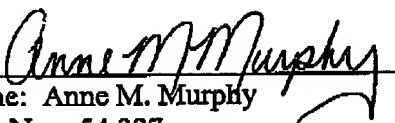
### Conclusions

In view of the above amendments and remarks, Applicant respectfully requests a Notice of Allowance. Please charge our Deposit Account No. 13-2725 in the amount of \$264.00 to cover the required additional claim fees due for a small entity as a result of these amendments.

Applicants request a telephone conference to advance the prosecution of this application if a Notice of Allowance will not be granted. The Examiner is requested to telephone the undersigned at the below-listed telephone number.

Respectfully submitted,  
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